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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,731

Applicant(s)

SMIT, JOHN

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 9-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

- [1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- [2] Claims 1-6 and 9-13 are pending in the application.
- [3] Applicant's amendment to the claims, filed on 6/27/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's arguments filed on 6/27/2005 have been fully considered.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

- [6] The rejection of claims 1-6 and 9-12 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "*Caulobacter crescentus* S-layer protein" (claim 1) or "an S-layer protein of said *Caulobacter crescentus*" (claim 9) is withdrawn in view of applicants' remarks. At p. 4 of the remarks, applicant admits the terms are meant to be interpreted as "S-layer proteins isolated from *Caulobacter crescentus* including variants of *Caulobacter crescentus* S-layer proteins." It is noted that applicant's remarks do not limit the S-layer protein isolated from *Caulobacter crescentus* to an endogenously expressed by *Caulobacter crescentus* S-layer protein, *i.e.*, the S-layer protein can be from any source as long as it is "isolated from *Caulobacter crescentus*." Also,

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applicant's remarks do not limit the intended variants of a *Caulobacter crescentus* S-layer protein, *i.e.*, the S-layer protein can be any variant of a *Caulobacter crescentus* S-layer protein. According to MPEP 2111, during examination, the examiner is to give claims their broadest reasonable interpretation. Thus, in accordance with applicant's remarks, an S-layer protein – from any source – recombinantly expressed and isolated from a *Caulobacter crescentus* host is considered to be a *Caulobacter crescentus* S-layer protein. As such, the examiner has interpreted the terms "*Caulobacter crescentus* S-layer protein" and "an S-layer protein of said *Caulobacter crescentus*" as encompassing *any* S-layer protein from any source.

[7] Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

[a] Claim 13 limits the *Caulobacter crescentus* S-layer protein of claim 1 or 9 to an S-layer protein comprising SEQ ID NO:5. Thus, the first component of claim 1 or 9 is a fragment of an S-layer protein comprising SEQ ID NO:5 comprising a secretion signal and the C-terminal 120 amino acids of an S-layer protein comprising SEQ ID NO:5. The claim is indefinite because it is unclear to the examiner as to those amino acids of SEQ ID NO:5 that are intended as being the "fragment." The specification discloses that the secretion signal of the *Caulobacter crescentus* S-layer protein of SEQ ID NO:5 is at the C-terminal end (p. 8, lines 16-19). In view of this teaching, it would appear that a secretion signal is encompassed by the C-terminal 120 amino acids. As such, it would appear that the "fragment" encompasses two secretion signals. However, based upon

the disclosure, this does not appear to be the intended meaning of the claims. It is suggested that applicants clarify the meaning of the claims by, for example, identifying the amino acids of SEQ ID NO:5 that are intended as being the "fragment."

[b] Claim 13 is indefinite in the recitation of "S-layer protein comprises the amino acid as set forth in SEQ ID NO:5" as it is unclear as to *the* amino acid of the sequence of SEQ ID NO:5 that the S-layer protein comprises, particularly as SEQ ID NO:5 would appear to comprise all 20 common amino acids. It is suggested that applicants clarify the meaning of the claim. In the interest of advancing prosecution, the claim has been interpreted as meaning that the S-layer protein comprises *any single* amino acid that is present in the sequence of SEQ ID NO:5.

Claim Rejections - 35 USC § 112, First Paragraph

[8] Claims 1-6 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection that is necessitated by amendment.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which

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applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Claims 1 (claim(s) 2-6 and 13 dependent therefrom) and 9 (claim(s) 10-13 dependent therefrom) recite the limitation of "fragment comprises a secretion signal and the C-terminal 120 amino acids of said *Caulobacter crescentus* S-layer protein." As a showing of support for the recited limitation, applicant points to fragments of SEQ ID NO:5 (p. 6, middle, of the response), *i.e.*, amino acids 622-1026, 690-1026, 784-1026, 892-1026, and 907-1026 of SEQ ID NO:5. Applicant's cited support is apparently at p. 9, lines 21-23 of the specification. However, while the cited disclosure may support specific fragments of SEQ ID NO:5, these specific fragments of SEQ ID NO:5 fail to support the recited limitation, which encompasses any fragment of any S-layer protein comprising a secretion signal and the C-terminal 120 amino acids of any S-layer protein. Applicant is invited to show support for the claimed limitation in the specification and claims as originally filed.

[9] The written description rejection of claims 1-6 and 9-13 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below. In view of the examiner's stated interpretation of claim 13, *i.e.*, the S-layer protein comprises *any single* amino acid that is present in the sequence of SEQ ID NO:5, claim 13 is being included in the instant rejection.

RESPONSE TO ARGUMENTS: Applicant argues the recited S-layer proteins are not any *Caulobacter* S-layer proteins, but are S-layer proteins from *Caulobacter*

crenscentus and applicant should not be required to characterize features of non-*Caulobacter crescentus* S-layer proteins.

Applicants' argument is not found persuasive. In this case, the genus of S-layer proteins is not limited to a *Caulobacter crescentus* S-layer protein, particularly in view of applicant's remarks, which clearly state that the terms "*Caulobacter crescentus* S-layer protein" and "an S-layer protein of said *Caulobacter crescentus*" are meant to encompass "variants of *Caulobacter crescentus* S-layer proteins." As noted above, in view of applicant's remarks and further in view of MPEP 2111, the terms "*Caulobacter crescentus* S-layer protein" and "an S-layer protein of said *Caulobacter crescentus*" have been interpreted as encompassing *any* S-layer protein from *any* source. In this case, applicants have disclosed specific fragments of SEQ ID NO:5, which fail to represent the variation within the genus, which encompasses any S-layer protein having any sequence of amino acids.

Applicant argues *Caulobacter crescentus* S-layer protein fragments that include a secretion signal have been disclosed and claimed in US Patent 6,210,948. According to applicant, he should not be required to describe additional species with respect to a claim element that is allegedly already taught in the prior art.

Applicant's argument is not found persuasive. Regarding the '948 patent, applicant is reminded that each patent application is examined on its own merits. The conclusions based on the allowed claims of another patent application, unrelated by priority lineage, are not considered to be pertinent to the instant rejection. While the examiner acknowledges that representative species are disclosed in the '948 patent,

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which appear to be identical to the species disclosed in the instant specification, these species fail to describe all members of the recited genus of S-layer proteins, which, as noted above, encompasses any S-layer protein having any sequence of amino acids.

Applicant argues claims 1 and 9 have been amended to characterize a structural feature of the genus of recited *C. crescentus* S-layer proteins, *i.e.*, the *C. crescentus* S-layer protein fragment comprises “the C-terminal 120 amino acids of said *Caulobacter crescentus* S-layer protein.”

The examiner acknowledges the amendment to the claims. However, other than defining the length of the *C. crescentus* S-layer protein fragment as being at least 120 amino acids, this limitation fails to structurally define the genus of fragments so as to distinguish the members of the genus from other S-layer protein fragments. Even in view of this limitation, the members of the genus are widely variant, encompassing a fragment of *any* S-layer protein, so long as it is at least 120 amino acids in length and includes a signal sequence.

Applicant argues that, given the alleged benefit of the claimed invention, the skilled artisan would consider the successful results disclosed in the Examples to be applicable to other *C. crescentus* S-layer protein fragments that include a secretion signal. Applicant argues the disclosed examples “address” the written description requirement, because, according to applicant, these examples are representative for the purpose of practicing the claimed methods.

As noted above, the disclosed species fail to represent the variation among the species, which in this case is substantial. In view of applicant’s remarks and in

accordance with MPEP 2111, the genus of recited *C. crescentus* S-layer protein fragments encompasses a fragment of *any* S-layer protein having *any* sequence of amino acids, so long as it is at least 120 amino acids in length and includes a signal sequence.

Applicant argues the instant case is distinguished from *UC California v. Eli Lilly* as the claimed invention is directed to cleaving insoluble fusion proteins of *C. crescentus* S-layer protein fragments containing a secretion signal, which are allegedly elements known in the art.

Applicants' argument is not found persuasive. Initially, it is noted that the claims are not limited to "elements known in the art" as asserted by applicants. Instead, the claims encompass a fragment of *any* S-layer protein having *any* sequence of amino acids, so long as it is at least 120 amino acids in length with a signal sequence. The genus encompasses fragments of known S-layer proteins, those S-layer proteins that have yet to be isolated, and any and all variants thereof.

Contrary to applicant's assertion, the facts of the *Lilly* case directly apply to the instant rejection. In *Lilly*, the Court held that the single representative species of a rat insulin cDNA failed to represent the entire genus of mammalian insulin cDNAs. Similarly, the disclosed species of S-layer protein fragments, *i.e.*, specific fragments of the *C. crescentus* S-layer protein of SEQ ID NO:5, fail to represent the genus of recited *C. crescentus* S-layer protein fragments, which, in view of applicant's remarks and in accordance with MPEP 2111, encompasses a fragment of *any* S-layer protein having *any* sequence of amino acids, so long as it is at least 120 amino acids in length with a

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signal sequence. Further, just as the Court in *Lilly* found that the functional description of a genus failed to define the structural features common to all members of the genus, the "functional" characteristic of the genus of recited first components fails to define the structural features common to all members of the genus of *C. crescentus* S-layer proteins.

Conclusion

[10] Status of the claims:

Claims 1-6 and 9-13 are pending.

Claims 1-6 and 9-13 are rejected.

No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs and alternate Fri, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656